UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE FLINT WATER LITIGATION	Case No. 5:16-cv-10444-JEL-MKM Hon. Judith E. Levy
This Document Relates To: *Gaddy et al. v. Flint et al.* *Meeks et al. v. Flint et al.*	 Case No. 5:17-cv-11166-JEL-MKM Case No. 5:17-cv-11165-JEL-MKM

REPLY IN SUPPORT OF DEFENDANTS VEOLIA NORTH AMERICA, LLC, VEOLIA NORTH AMERICA, INC., AND VEOLIA WATER NORTH AMERICA OPERATING SERVICES, LLC'S MOTION TO EXCLUDE THE TESTIMONY AND REPORT OF AARON SPECHT, PH.D.

CONTROLLING OR MOST APPROPRIATE AUTHORITIES

Baker v. Chevron U.S.A. Inc., 533 F. App'x 509 (6th Cir. 2013)

Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993)

Dombrowski v. Gould Electronics, Inc., 31 F. Supp. 2d 436 (M.D. Pa. 1998)

Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997)

Nelson v. Tenn. Gas. Pipeline Co., 243 F.3d 244 (6th Cir. 2001)

United States v. Smallwood,
No. 5:08-CR-38, 2010 WL 4168823 (W.D. Ky. Oct. 12, 2010)

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INTRODUCTION

Dr. Specht is Plaintiffs' expert on bone lead measurements; he claims that his measurements [redacted]. But his measurements are not reliable under Rule 702 and *Daubert*. Contrary to Plaintiffs' contention, VNA does not simply "disagree[]" with Dr. Specht's opinion, and this is not a "battle of the experts." Pls. Response to VNA Mot. to Exclude Specht (Response) 2, ECF No. 368, PageID.23328. Rather, Dr. Specht's *own* published, peer-reviewed research concludes that his pXRF device does not accurately measure bone lead in children. Dr. Specht also admits that scientists have not reached a conclusion about what constitutes an elevated level of lead in a child's bones—so even if his pXRF device did produce accurate results, [redacted]. Yet now, in litigation, Dr. Specht claims that the measurements that he previously said were not accurate in fact are accurate, and that [redacted], a term he admits has no settled meaning.

Plaintiffs fail to come to grips with Dr. Specht's own published research and admissions, which show that his litigation-driven opinion here is unreliable. Critically, Plaintiffs have not cited a single scientific paper validating the use of pXRF on children—not by Dr. Specht or by anyone else. Instead, evidence provided by others in this litigation strongly suggests that the pXRF device should *not* be used

on children and has the potential to cause harm by exposing them to unnecessary radiation.

Plaintiffs attempt to sidestep Dr. Specht's published research by claiming that it involved an outdated methodology and that he has "improved" his approach for this case, primarily by changing the measurement time. The problem is that Dr. Specht has not shown that his new approach is reliable. He never subjected the revised methodology to the scrutiny of the scientific community: Its use on children has not been tested or peer reviewed; it does not have known error rates or standards; and it is not generally accepted. Plaintiffs ask the Court to find that Dr. Specht has solved all previous problems with his research, and that the use of his pXRF device on children has become generally accepted, based on nothing more than his own say-so. The Court should not do that.

Further, Dr. Specht acknowledged that his tests cannot show that any Plaintiff [redacted]. As he put it, "[t]o my knowledge, there has been no scientific conclusion as to what the usual bone lead would be versus a high bone lead." Ex. 3, Specht Dep. (Dep.) at 333:24-334:10. Plaintiffs have no response to Dr. Specht's admission, which renders his [redacted] opinion unreliable. Dr. Specht attempted to draw comparisons to bone lead measurements on children in China and Canada, but VNA pointed out that those

comparisons are fundamentally flawed, and Plaintiffs have no response to that, either.

Even if everything about Dr. Specht's pXRF testing were reliable, moreover, the tests could not support liability against VNA. The fundamental problem is that Dr. Specht cannot trace lead detected in Plaintiffs' bones to any particular source or any particular time, including the Flint water crisis generally or the period after VNA began its engagement specifically. Plaintiffs say that their other experts connect the dots on causation, but that is just not true; they do not trace the source of lead in Plaintiffs' bones, either.

Relatedly, to support his reliance on bone lead measurements, Dr. Specht attempts to discredit the usefulness of the standard measure for lead exposure—blood lead. He asserts that the half-life of lead in children's blood is less than one week and therefore is difficult to measure. Plaintiffs fail to identify any reliable basis for Dr. Specht's opinion that blood lead has a half-life of less than one week. Dr. Specht did not review the scientific literature on blood lead half-lives, but instead cherry picked and embellished two of his own studies that touched on the issue.

ARGUMENT

I. Dr. Specht Did Not Employ A Reliable Methodology For Measuring Bone Lead In Children

Under Rule 702 and *Daubert*, Plaintiffs bear the burden of establishing by a preponderance of the evidence that Dr. Specht's pXRF device is a reliable

methodology for measuring bone lead in children. *Nelson v. Tenn. Gas. Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Plaintiffs have not carried their burden. All of the reliability factors—testing, peer review and publication, existence of known error rates and standards, and general acceptance, Br. in Supp. of VNA Mot. to Exclude Specht (VNA Br.) 10, ECF No. 343, PageID.21602—instead confirm that Dr. Specht's pXRF device is unreliable when used on children.

A. pXRF Has Been Tested On Children In Peer-Reviewed Research And Has Been Found To Be Unreliable

1. Dr. Specht's Own Research Has Demonstrated That pXRF Testing Does Not Accurately Measure Bone Lead In Children

Dr. Specht's use of a pXRF device to measure bone lead is unreliable for a simple reason—his own published, peer-reviewed research says so. Specifically, Dr. Specht tested the device against a more established technology (KXRF) and concluded that pXRF does not accurately measure bone lead in children. *See* VNA Br. 12-16, PageID.21604-21608; Ex. 9, A. Specht et al., *XRF-Measured Bone Lead (Pb) as a Biomarker for Pb Exposure and Toxicity Among Children Diagnosed with Pb Poisoning*, 21 Biomarkers 347 (2016) at 2, 6-7 (Specht 2016), ECF No. 343-10, PageID.21695, 21699-21700; Ex. 11, A. Specht et al., *Childhood Lead Biokinetics and Associations with Age Among a Group of Lead Poisoned Children in China*, 29 J. Expo. Sci. Env't Epidemiol. 416 (2019) at 8 (Specht 2019), ECF No. 343-12, PageID.21720. As recently as 2019—at the same time Plaintiffs were undergoing

pXRF testing—Dr. Specht acknowledged in his published research that his pXRF device has *not* been validated for use on children and that "further work" is needed to understand this "new measurement system." Ex. 11, Specht 2019 at 8, PageID.21720. Dr. Specht's published research attributed the inaccuracy in measuring bone lead in children to two factors: children having thicker soft tissue covering their tibias, and children having different bone composition than adults. Ex. 9, Specht 2016 at 6-7, PageID.21699-21700.

Plaintiffs do not dispute any of that. Instead, they argue that Dr. Specht has now "fully verified" his pXRF device for use *on children*, based on recent studies performed *on birds and adults*. Response 12-13, 30-31, PageID.23338-23339, 23356-23357. But VNA already explained why the bird and adult studies are irrelevant to children—the studies fail to validate the use of pXRF on subjects with thicker tissue, and they do not purport to address children's unique bone composition. VNA Br. 17-18, PageID.21609-21610. Those are the exact problems Dr. Specht identified in his published research about using the pXRF device on children. Dr. Specht cannot rely on bird and adult studies to validate the use of pXRF on children because "there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146-47 (1997); *see C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 835-36 (7th Cir. 2015) (affirming exclusion of testimony of expert who relied on studies involving

exposures among adult workers and lab rats that did not translate to children resulting in "an analytical gap too wide to be bridged").[1]

Plaintiffs hypothesize that perhaps the tests are accurate for them—even if they are not accurate for children in general—because they have uniquely thin tissue. That is, Dr. Specht's published research concludes that his pXRF device does not produce accurate results in part because children have thicker tissue overlaying their tibias, Ex. 9, Specht 2016 at 6-7, PageID.21699-21700, so Plaintiffs suggest that their own tissue may be thinner and fault VNA for failing to take discovery on their tissue thickness, Response 31, PageID.23357. But VNA *did* seek discovery on their tissue thickness—it questioned Dr. Specht at his deposition on that issue. Dr. Specht testified that he has not calculated or otherwise measured Plaintiffs' tissue thickness. VNA Br. 14, PageID.21606; Dep. 148:15-149:18. The burden is on Plaintiffs to prove that Dr. Specht's use of pXRF on them is reliable. Plaintiffs have not met that burden, because all they have is speculation that they may have thinner tissue overlaying their tibias than typical children. And even if Plaintiffs had thinner tissue,

[1] *See also, e.g.*, *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1046, 1051 (S.D. Ill. 2001) ("While researchers might reliably extrapolate from animal studies sometimes, . . . the type of extrapolations [the proffered experts] divine from these particular animal studies—with all their dissimilarities—involve too many and too great of analytical gaps between the data and the opinions proffered.").

that does not address the second problem identified in Dr. Specht's research—children's unique bone composition.

2. Plaintiffs Have Not Otherwise Established That The Testing And Peer-Review Factors Are Satisfied

Plaintiffs argue that *Daubert*'s testing and peer-review factors are satisfied by the mere fact that Dr. Specht tested his pXRF device and published the results—regardless of what the results say. Response 21, 24-25, PageID.23347, 23350-23351. The problem, of course, is that the results say that the pXRF device is not reliable when used on children. So Plaintiffs shift gears, casting aside the published results, and relying instead on Dr. Specht's supposedly "improved" methodology used in this litigation. *Id.* at 27, PageID.23353.[2] The problem with that approach is that Dr. Specht's new methodology has not been tested or peer reviewed by anybody—so Plaintiffs cannot claim that it has any indicia of scientific reliability. *See, e.g., Sardis v. Overhead Door Corp.*, —F.4th—, No. 20-1411, 2021 WL 3699753, at *16 (4th Cir. Aug. 20, 2021) (in the absence of "testing," "peer review[]," or "some basis" outside the expert's own experience "to assess the level of reliability, expert opinion testimony can easily, but improperly devolve into

[2] Plaintiffs say VNA made no "mention" of the modifications made by Dr. Specht in Flint. Response 27, PageID.23353. That is not true; in its opening brief, VNA explained that Dr. Specht experimented with three-minute readings in Flint, which were not subject to peer review or otherwise validated for use on children. *See* VNA Br. 7, 18-19, PageID.21599, 21610-21611.

nothing more than proclaiming an opinion is true 'because I say so'") (internal quotation marks and citation omitted).

In order to conclude that Dr. Specht's new methodology overcame the problems associated with measuring bone lead in children that he identified in his published research, the Court would need some evidence to support that conclusion (such as testing and peer review). And Plaintiffs simply have not provided that evidence. The scientific method is based on "generating hypotheses and testing them." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993) (internal quotation marks omitted). As Plaintiffs' own case law explains, the "'key' is whether 'the theory and procedures have been submitted to the scrutiny of the scientific community.'" *United States v. Gissantaner*, 990 F.3d 457, 464 (6th Cir. 2021) (quoting *United States v. Bonds*, 12 F.3d 540, 559 (6th Cir. 1993)). The pXRF procedures used by Dr. Specht to measure bone lead in children in this litigation have never been submitted to the scrutiny of the scientific community or otherwise validated. Plaintiffs have provided no evidence to the contrary.

All Dr. Specht (or someone else) had to do was use the same validation methods that Dr. Specht used in his published research. In his published research, Dr. Specht attempted (unsuccessfully) to validate the use of pXRF on children by comparing pXRF measurements to a known standard—KXRF measurements. VNA Br. 14-16, PageID.21606-21608. That is how Dr. Specht consistently has tried to

validate his pXRF device, including in his bird and adult studies. VNA Br. 17, PageID.21609; Ex. 12, A. Specht et al., *Feasibility of a Portable X-ray Fluorescence Device for Bone Lead Measurements of Condor Bones*, 615 Sci. of the Total Env't 398 (2018), ECF No. 343-13; Ex. 13, A. Specht et al., *Lead Exposure Biomarkers in the Common Loon*, 647 Sci. of the Total Env't 639 (2019), ECF No. 343-14. Yet despite attempting to "improve[]" his pXRF methodology for use on children in this litigation, Dr. Specht never attempted to validate the supposedly "improved" methodology against any known standard, KXRF or otherwise, and so he has not shown that it accurately measures bone lead in children.[3] Without any validation, the methodology is unreliable. *See, e.g.*, *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997) (an expert must be "as careful as he would be in his regular professional work outside his paid litigation consulting"); Response 22, PageID.23348 (conceding that exclusion is appropriate when "'[n]obody . . . has

[3] In late 2020, Dr. Specht's colleague and former supervisor, Dr. Linda Nie at Purdue, wrote to Dr. Specht that she was "not confident" about using pXRF on children based on their 2016 and 2019 China studies and inquired about his litigation work in Flint. Ex. 24, HU005667. Dr. Specht responded that restricting the China data to children older than four years of age—like Plaintiffs here—"actually made the data worse" as to the accuracy of the pXRF device, and "[i]t would be good if we could test more kids using the KXRF and pXRF together." Ex. 25, HU005714. Despite privately acknowledging that it would be "good" to validate pXRF against KXRF as to children, Dr. Specht never did so.

ever tested' the expert's theory") (quoting *Wilden v. Laury Transp., LLC*, 901 F.3d 644, 649 (6th Cir. 2018)).

Dr. Specht has published only one paper that involved the three-minute pXRF measurements he used in Flint—his 2021 study on *adults* in Indiana. VNA Br. 17-18, 22, PageID.21609-21610, 21614; Ex. 14, X. Zhang, A. Specht et al., *Evaluation of a Portable XRF Device for In Vivo Quantification of Lead in Bone Among a US population*, 753 Sci. of the Total Env't No. 142351 (2021) (Zhang 2021), ECF No. 343-15. But Dr. Specht's adult study is irrelevant to children. *See* pp. 4-5, *supra*. And in any event, Dr. Specht's adult study compared three-minute and five-minute measurement times and found that five-minute measurements were better: They improved the "sensitivity" of the pXRF device and "reduced the measurement uncertainty." Ex. 14, Zhang 2021 at 6, PageID.21753. That hardly is a ringing vindication of three-minute measurements in adults, let alone children. Plaintiffs argue that *Daubert* does not require the "'best methodology,'" only a reliable methodology. Response 32 n.16, PageID.23358 (quoting *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999)). But Dr. Specht has never validated the use of pXRF on children, regardless of measurement time.

Plaintiffs argue that the pXRF procedures used by Dr. Specht in this litigation are reliable because they are a "natural outgrowth" of his "ordinary testing methodology." Response 38-39, PageID.23364-23365. Again, the problem is that

Dr. Specht's published research says that his previous testing methodology is not reliable when used on children, and he never attempted to validate the new methodology he used in this litigation. Plaintiffs have not cited any authority where an expert took a methodology that his own research failed to validate, and tweaked it for use in litigation without any further testing or peer review, and the court found the methodology reliable. As Plaintiffs' own case law explains, *Daubert* might allow "a slight modification of an otherwise reliable method," *United States v. Jones*, 965 F.3d 149, 160 (2d Cir. 2020) (internal quotation marks omitted), but Dr. Specht's pXRF device has never been validated for use on children and thus is not "otherwise reliable."

Plaintiffs further argue that flaws identified in the peer review process go to the weight of the evidence, not its admissibility. Response 26, PageID.23352. That misses the point. Unlike the cases cited by Plaintiffs, Dr. Specht did not submit a study for peer review only to have peers raise concerns.[4] Here, *Dr. Specht and his co-authors* concluded that his pXRF device does not accurately measure bone lead in children—and the reviewers apparently agreed with that conclusion. When an expert seeks to offer opinions that are contrary to his own published research, the

[4] *See, e.g.*, *Bonds*, 12 F.3d at 559 (flaws "uncovered by peer review" generally go to weight); *United States v. Romero-Lobato*, 379 F. Supp. 3d 1111, 1119 (D. Nev. 2019) ("unfavorable views" from peers generally go to weight).

opinions are unreliable. *See, e.g.*, *United States v. Smallwood*, No. 5:08-CR-38, 2010 WL 4168823, at *5 (W.D. Ky. Oct. 12, 2010), *aff'd*, 456 F. App'x 563 (6th Cir. 2012) (excluding expert testimony because the expert's "own studies appear[ed] to contradict his opinion" and also "acknowledge[d] that there was a lack of reliable data").

In short, Rule 702 and *Daubert* preclude Dr. Specht from using a bone lead test that his own published research found to be unreliable when used on children. As the Sixth Circuit explained in *Gissantaner*, testability focuses on "whether a method can be 'assessed for reliability,'" while the remaining *Daubert* factors, including peer review, "all turn in one way or another on what actual testing of the theory reveals in terms of reliability." 990 F.3d at 464 (citation omitted). Dr. Specht's testing of his pXRF device in peer-reviewed, published research reveals that his pXRF device does not accurately measure bone lead in children.

3. Dr. Specht's pXRF Measurements Cannot Be Replicated

To perform his pXRF measurements, Dr. Specht purchased pXRF devices manufactured by Thermo Fisher that are normally used for industrial purposes, then modified both the devices themselves and their software to attempt to measure lead in children's bones. Plaintiffs have not meaningfully refuted VNA's showing that Dr. Specht's measurements cannot be replicated due to obstacles in obtaining both

the device itself and its customized software. VNA Br. 19-21, PageID.21611-216113.

With respect to the pXRF devices themselves, Thermo Fisher has made clear that it will not sell the devices for use on humans, let alone children, outside the context of academic research approved and supervised by a university's institutional review board. In fact, Thermo Fisher recently directed Plaintiffs and Dr. Specht to stop using the device for litigation purposes:

> [W]e write to advise you that Thermo Fisher has never marketed the XL3t [pXRF device] for any *in vivo* diagnostic use (including, without limitation, any such use to measure bone lead levels in living persons), nor have we sought or obtained FDA approval for such use. While we are aware of a limited number of occasions on which we have supported academic research into the use of Thermo Fisher handheld XRF devices to measure bone lead, such research was, to our knowledge, approved by a university IRB in each instance. Your use of the XL3t does not appear to arise in the context of academic research, and we are not aware of any IRB approval for your activities.

Ex. 26, TFS00396.[5] When other plaintiffs' counsel tried to purchase pXRF devices to take measurements for settlement purposes, Thermo Fisher refused to sell them the devices:

[5] Dr. Specht never obtained institutional review board approval for his litigation work in Flint, including for the three-minute pXRF readings that Dr. Specht used on children for the first (and only) time in Flint. *See, e.g.*, Ex. 27, Ltr. from Genevieve Aguilar, Assoc. Attorney, Harv. Univ., to David Rogers, Member, Campbell Conroy O'Neil, P.C. 2 (May 28, 2021) ("[T]here are no human subjects research studies that the HSPH [Harvard T.H. Chan School of Public Health] IRB has approved that involve the use of the pXRF as a radiation source in Harvard owned or controlled facilities."; "Harvard disagrees with any suggestion that the HSPH IRB or related-

> Thermo Fisher does not market the XL3t for purposes similar to your intended use (*i.e.*, testing living persons' levels of bone lead in a non-research context), and, as such, we must decline your offer to purchase these instruments for such use. In the course of these discussions, Thermo Fisher has become aware of the use of the XL3t by certain other firms involved in the Flint litigation—I understand that we have investigated these matters and have taken appropriate measures to clarify the device's intended use.

Ex. 29, TFS00688.[6] Dr. Hannah-Attisha and Dr. Reynolds have also raised serious concerns about subjecting children to any amount of radiation for a test with no real benefit. VNA Br. 25-26, PageID.21617-21618.

Plaintiffs argue that it would be "easy to replicate or test" Dr. Specht's pXRF results. Response 23, PageID.23349. But they never mention that Thermo Fisher directed them to stop using the pXRF device and refuses to sell the device for use in litigation. They simply ignore the fact that the device is unavailable and lacks FDA approval. *Id.* at 23-24, PageID.23349-23350. A methodology is not testable or

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radiation safety committee at Harvard has approved the use of the pXRF as a radiation source for human subjects research at Harvard."). Dr. Specht failed to obtain IRB approval for his litigation work in Flint despite previously reassuring Thermo Fisher that he "always" obtains approval "prior to doing this type of work," even on animals. Ex. 28, HU005601. Moreover, Dr. Specht admits that he failed to obtain signed consent forms from Plaintiffs' parents before subjecting Plaintiffs to his three-minute pXRF measurements. Dep. 508:2-10.

[6] When Dr. Specht helped Plaintiffs rent pXRF devices from Thermo Fisher in late 2020 and early 2021, they apparently failed to inform Thermo Fisher that they intended to use the devices to diagnose children as lead-exposed for litigation purposes. Dr. Specht merely told Thermo Fisher that he had "some potential collaborators who are interested in using the device short term for *environmental surveillance*." Ex. 30, TFS00154 (emphasis added).

replicable (or otherwise reliable) when the device manufacturer has disavowed the particular use of its device and refuses to sell the device for that purpose. Because the device is unavailable, "[s]omeone else using the same data and methods" cannot replicate the result. *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005).

Dr. Specht's customizations to the pXRF device and its software make testing or replication even less realistic. Plaintiffs argue that settings are identified in Dr. Specht's articles and that he would produce them on request. Response 23-24, PageID.23349-23350. But the recent experiences of the *Washington* and *Chapman* plaintiffs and their experts refutes Plaintiffs' assertions. Dr. Specht's articles provided only basic information on settings, and Dr. Todd and Dr. Jepson were unable to replicate his pXRF testing because he did not share his protocols (including details of his calibration methods and process), despite committing to do so. VNA Br. 21, PageID.21613.

Plaintiffs fault VNA for not testing Dr. Specht's methodology itself, Response 24, PageID.23350, but that is not VNA's burden, *Nelson*, 243 F.3d at 251. VNA also had many reasons for not undertaking the futile gesture of attempting to perform pXRF testing of its own: Thermo Fisher will not sell the pXRF device for use in litigation; the device is not FDA approved to diagnose individuals as lead-exposed; VNA cannot ethically subject children to another dose of radiation; it is

inconceivable that parents would permit such testing; and Dr. Specht's published, peer-reviewed research already shows that the device does not reliably measure bone lead in children.[7] *Daubert* asks whether a methodology "can be (and has been) tested." 509 U.S. at 593. Dr. Specht's pXRF device has been tested for use on children and found to be unreliable. There was no need for VNA to test again using a method that has never been validated—even if it could have done so.

B. pXRF Has Significant Error Rates, And No Standards Control Its Operation

Dr. Specht's published research found that the use of pXRF on children has too high of an error rate to be reliable. VNA Br. 22, PageID.21614; Ex. 9, Specht 2016 at 7, PageID.21700; Ex. 11, Specht 2019 at 8, Page ID.21720. As Dr. Specht wrote as recently as 2019, there are only "limited" studies of how children absorb lead in the first place, which "makes it difficult to assess the abilities of the device in comparison to some standard." Ex. 11, Specht 2019 at 8, Page ID.21720. And Dr. Specht's new approach for litigation does not solve the problem of lack of

[7] Plaintiffs rely heavily on *Dzielak v. Whirlpool Corp.*, No. 12-cv-89, 2017 WL 1034197 (D.N.J. Mar. 17, 2017). Response 23-24, PageID.23349-23350. In *Dzielak*, however, the court admitted expert testimony based on proprietary software that was a "variant of a known technique" and was "proven reliable outside of the context of litigation," including in a peer-reviewed paper, over 100 commercial studies, and in legal scholarship. 2017 WL 1034197, at *7. The proprietary software at issue in *Dzielak* also was not used in connection with a device that the manufacturer refused to sell for that purpose.

standards for use of pXRF on children. VNA Br. 22, PageID.21614; Ex. 9, Specht 2016 at 7, PageID.21700; Ex. 11, Specht 2019 at 8, Page ID.21720.

Plaintiffs do not dispute that no standards exist to control the operation of Dr. Specht's pXRF device. Yet they argue that the error rate is "exceptionally low," relying on the uncertainty values spit out by Dr. Specht's pXRF device with each bone lead measurement. Response 9-10, 27-33, PageID.23335-23336, 23353-23359. When Dr. Specht's pXRF device takes a bone lead reading, it reports both a measurement and an uncertainty value representing the amount, plus or minus, by which it determines that the actual bone lead level may differ from the measurement. VNA Br. 31, PageID.21623.

The uncertainty values produced by Dr. Specht's pXRF device do not show that his methodology has low error rates. First, an expert cannot validate a methodology by pointing out that the methodology itself claims to have a low error rate. Plaintiffs simply assume that the uncertainty values spit out by Dr. Specht's pXRF device are correct, but it is the reliability of that device that is in question. When it comes to using pXRF on children, Dr. Specht's published research has not validated the accuracy of the uncertainty values any more than it has validated the bone lead measurements themselves. Plaintiffs offer nothing more than Dr. Specht's say-so that a child's real bone lead level actually falls within the uncertainty range

generated by his modified pXRF device. That is not enough to establish reliability under *Daubert*. *Joiner*, 522 U.S. at 146.

Dr. Specht acknowledges that the uncertainty values generated by his pXRF device are based on a novel methodology that can produce widely varying results. Dr. Specht's modified pXRF device generates uncertainty values (and the bone lead measurements themselves) using "background subtraction," which takes the data generated by the measurement and attempts to subtract out sources of background interference (like overlaying tissue). Dep. 131:5-133:9. In their research applications, Dr. Specht and his colleagues describe the background subtraction process as a "novel method" for calibrating the pXRF device. Ex. 31, BU000328 at BU000346. And Dr. Specht admits that errors in estimating the "background" can cause "the numbers [to] be off by . . . a wide margin." Dep. 246:10-248:10. Plaintiffs' reliance on uncertainty values to show low error rates is therefore misplaced; a methodology cannot validate itself and Dr. Specht has never independently validated the accuracy of his uncertainty values when measuring bone lead in children.[8]

[8] The uncertainty values for Plaintiffs' bone lead measurements are suspect on their face. For example, when Dr. Specht used three-minute pXRF measurements in his 2021 study on adults in Indiana, he reported mean (average) uncertainty values of 4.9 µg/g for adults with thinner tissue and up to 10.6 µg/g for adults with thicker tissue. Ex. 14, Zhang 2021 at 4, PageID.21751. Yet Dr. Specht claims that Plaintiffs' three-minute pXRF measurements here had uncertainty values of [redacted], Response 29, PageID.23355, despite previously

Second, Dr. Specht's published research makes clear that the accuracy issues with using pXRF on children have nothing to do with uncertainty values. Dr. Specht's published research concluded that pXRF does not accurately measure bone lead in children—and not because uncertainty values were too high. In fact, pXRF and KXRF measurements had similar uncertainty values. Ex. 11, Specht 2019 at 8, PageID.21720. Yet Dr. Specht wrote that pXRF and KXRF produce different results because they are "likely" "sampling different portions of the bone," that there are only "limited" studies of how children absorb and store lead, and that "further work needs to be done to determine exactly what biomarker is being measured using pXRF, and how it may relate to the traditional measurement of bone [lead] and the biokinetics of [lead] in the body." *Id.* These conclusions of Dr. Specht himself establish definitively that the uncertainty values do not fully capture the range of problems associated with the use of pXRF on children. Nor do they establish any standard for the operation of the pXRF device.

Plaintiffs argue that error rates "generally . . . at most affect the weight of the evidence." Response 28, PageID.23354. That is wrong; error rate is a key factor for evaluating admissibility of expert testimony under Rule 702 and *Daubert*. *Nelson*,

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acknowledging that children have thicker tissue overlaying their tibias than adults, Ex. 9, Specht 2016 at 6-7, PageID.21699-21700. The lack of any explanation for this highly suspect discrepancy highlights the absence of any standards for Dr. Specht's pXRF methodology.

243 F.3d at 251 n.5 (citing *Daubert*, 509 U.S. at 593-94). And here, that factor weighs heavily against finding reliability, because Dr. Specht's published research found that the use of pXRF on children has too high of an error rate to be reliable without further work, which has not occurred. VNA Br. 22, PageID.21614; *see* pp. 4-6, *supra*. That is an admissibility issue under *Daubert*, not a weight issue for the finder of fact.[9]

C. pXRF Is Not Generally Accepted For Measuring Bone Lead In Children

VNA's opening brief explained why Dr. Specht's use of pXRF devices to measure bone lead in children should be viewed with great skepticism. VNA Br. 23-27, PageID.21615-21619. Not a single scientific paper has validated the use of pXRF for that purpose; no one besides Dr. Specht and his colleagues has even attempted to use pXRF to measure bone lead in anyone, let alone children; a variety of scientists and medical doctors have criticized Dr. Specht's use of pXRF in this litigation (including Dr. Hu, Dr. Hannah-Attisha, Dr. Reynolds, Dr. Todd, and Dr.

[9] In a footnote, Plaintiffs suggest that it is *VNA*'s burden to establish that Dr. Specht's use of pXRF on children has an unacceptably high error rate. Response 30 n.15, PageID.23356. Plaintiffs are incorrect; the burden rests with them. *Nelson*, 243 F.3d at 251. The cases Plaintiffs cite, Response 30 n.15, PageID.23356, are not to the contrary. *See United States v. Sullivan*, 246 F. Supp. 2d 700, 703 (E.D. Ky. 2003) (holding that the proponent of expert testimony "has the burden of establishing its reliability under *Daubert*" and crediting the proponent's evidence of a "minimal error rate," which the moving party failed to dispute); *United States v. Mitchell*, 365 F.3d 215, 240 (3d Cir. 2004) (recognizing an exception when the proponent of the expert opinion was being asked to prove a negative, which is not the case here).

Jepsen); the device manufacturer has directed Dr. Specht to stop using its device in this way; and Dr. Specht's pXRF device has not been approved by the FDA for use outside (or inside) the courtroom to diagnose individuals as lead-exposed. *Id.*

Dr. Specht also used his pXRF device to measure Plaintiffs' bone lead before registering the device with the State of Michigan, as Michigan law requires. *See* Mich. Admin. Code R. 333.5037. Dr. Specht's use of an unregistered radiation machine is a misdemeanor under Michigan law. Mich. Comp. Laws § 333.2261. When the Michigan Occupational Safety & Health Administration (MIOSHA) found out about Dr. Specht's use of the pXRF device in Flint, it raised immediate concerns because "XRF machines are typically used to scan materials to determine the element content" and "[t]he current use of the XRF machines is a newer type of use." Ex. 32, MIOSH, General Activity Report (Mar. 18, 2021). MIOSH ultimately found that Dr. Specht and Plaintiffs' counsel had violated Michigan law by operating an unregistered radiation machine and doing so without proper safety protocols. *See* Ex. 33, MIOSH, X-Ray Inspection Report (May 4, 2021); Ex. 34, MIOSH, X-Ray Inspection Report (June 25, 2021). This is yet another reason that the Court should not approve Dr. Specht's use of the device in this case as reliable.

Plaintiffs do not provide any evidence that pXRF is generally accepted for measuring bone lead in children. Plaintiffs rely solely on Dr. Specht's assurances at his deposition that he "feel[s]" like pXRF is a "very set" methodology because

"[w]e've done so many papers on [pXRF] that it's fairly widely understood to be something that's possible to do with this device." Response 35, PageID.23361 (citing Dep. 62:22-63:3). Yet the published papers referenced by Dr. Specht conclude that pXRF has *not* been validated for use on children. VNA Br. 12-16, PageID.21604-21608. Thus, while Plaintiffs try to discount the voluminous evidence provided by VNA, they have not provided any evidence of their own to establish that the use of pXRF on children is generally accepted.

Although Plaintiffs tout the supposedly "improved" methodology that Dr. Specht used in this litigation, Dr. Specht has never subjected his litigation work to the scrutiny of the scientific community—so it cannot be generally accepted. Plaintiffs provide no evidence that *anyone* besides Dr. Specht accepts that pXRF has been validated for use on children. And Dr. Specht's unsupported assertions cannot establish reliability by themselves. *Joiner*, 522 U.S. at 146; *see Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1202 n.13 (11th Cir. 2010) ("[O]ther than [the expert's] own unsupported . . . assertion . . . , there is no evidence that [his] theory is generally accepted in the relevant scientific community."); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) ("[*Daubert*] requires some objective, independent validation of the expert's methodology. The expert's assurances that he has utilized generally accepted scientific methodology [are] insufficient.").

Plaintiffs attempt to water down the "general acceptance" factor, arguing that it does not require "uniform[ity]" or "consensus," and that the relevant scientific community can be "small." Response 34-35, PageID.23360-23361. But at a minimum, Plaintiffs must show that *somebody* besides Dr. Specht accepts pXRF as reliable for measuring bone lead in children. For example, Plaintiffs cite the Second Circuit's conclusion in *Jones* that a methodology was generally accepted even though the expert's laboratory was the "only laboratory" using the methodology. Response 35, PageID.23361. But in that case, the methodology had undergone "external validation and peer review" and had been admitted in courts more than 40 times. *Jones*, 965 F.3d at 158-60.

Plaintiffs' opposition suffers from a complete failure of proof as to general acceptance, and all of the evidence points the other way. The lack of general acceptance, like all the other *Daubert* admissibility factors, weighs heavily against admitting Dr. Specht's pXRF measurements.

II. Dr. Specht's Opinions About The Significance Of Plaintiffs' Bone Lead Measurements Are Unreliable

Plaintiffs have not shown that Dr. Specht's opinion that [redacted] is reliable. Plaintiffs barely address this critical part of Dr. Specht's opinion in their brief.

A. There Is No Established Standard For Quantifying Elevated Bone Lead Levels

Dr. Specht has not identified any reliable standard against which to compare his measurements of lead in Plaintiffs' bones. There are no regulatory reference values for bone lead, and Dr. Specht admits that, "[t]o [his] knowledge, there has been no scientific conclusion as to what the usual bone lead would be versus a high bone lead." VNA Br. 28-30, PageID.21620-21622; Dep. 333:24-334:10. Plaintiffs never explain how Dr. Specht can reliably opine that Plaintiffs' bone lead levels show that [redacted] when he admits that there is no scientific conclusion as to what constitutes an elevated level of bone lead.

Plaintiffs ignore Dr. Specht's admission. In a footnote, they fault VNA for not providing a citation for a statement in its brief that "Dr. Specht admits that there are no reliable benchmarks." Response 41 n.19, PageID.23367. But that statement was the topic sentence to an entire paragraph that discusses Dr. Specht's admission and related statements in his published research, and the paragraph is replete with citations. VNA Br. 29, PageID.21621. For example, in his 2016 and 2019 papers, Dr. Specht conceded that, because not many bone lead studies have been performed on children, "[t]here is a significant gap in understanding . . . the usefulness of bone [lead] as a biomarker for [lead] exposure and toxicity among children," Ex. 9, Specht 2016 at 2, PageID.21695, and "it [is] difficult to assess the abilities of the device in

comparison to some standard," Ex. 11, Specht 2019 at 8, PageID.21720. Plaintiffs do not address any of these concessions.

Plaintiffs also have no good response to *Dombrowski v. Gould Electronics, Inc.*, 31 F. Supp. 2d 436 (M.D. Pa. 1998). The court in that case excluded bone lead measurements (using KXRF) because "there is no agreed upon standard against which to test the readings," which made it "impossible to decide the significance of what the readings might happen to be." *Id.* at 442. Plaintiffs suggest that comparing the results to a reliable standard simply "wasn't possible at that time." Response 45, PageID.23371. But it is not possible now either, as Dr. Specht's admission and published research make clear. Or, as Dr. Hu put it, "[redacted] compared to what?"; "[t]here are no standards for bone lead levels in either children or adults." VNA Br. 29, PageID.21621 (quoting Ex. 15, Hu Dep. 385:8-14, 386:1-7).

B. The China And Canada Studies Do Not Support Dr. Specht's Opinions

In the absence of any established standard for what constitutes an elevated or "substantial" bone lead level, Dr. Specht attempts to draw comparisons to bone lead readings taken on children in China and Canada. VNA's opening brief demonstrated why these comparisons are unreliable—Plaintiffs' reported bone lead levels [redacted], while the Canada study used KXRF technology, not pXRF, and involved children who would be expected to have

lower background exposures than children in Flint because of Flint's industrial history and the prevalence of lead paint in Flint's older homes. VNA Br. 32-38, PageID.21624-21628.

Plaintiffs offer no substantive defense of Dr. Specht's comparisons to the data from China and Canada. Instead, they argue that Dr. Specht is free to make whatever comparisons he wants unless his numbers are "pull[ed] . . . from thin air." Response 42, PageID.23368 (quotation marks and citations omitted). That is not the *Daubert* standard. An opinion is unreliable if "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. In *Joiner*, the Supreme Court affirmed the exclusion of expert testimony because "the studies upon which the experts relied were not sufficient . . . to support their conclusions that [the plaintiff's] exposure to PCB's contributed to his cancer." *Id.* at 146-47. The same is true here.

The Sixth Circuit routinely excludes expert opinions where there is simply too great a gap between cited studies and the opinions offered. *See, e.g.*, *Baker v. Chevron U.S.A. Inc.*, 533 F. App'x 509, 520 (6th Cir. 2013) (affirming exclusion of opinion that benzene caused plaintiffs' cancer based on district court's "exhaustive[] review" of expert's cited studies, which generally had higher exposures or statistically insignificant results); *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 679-80 (6th Cir. 2011) (affirming exclusion of opinion that benzene caused plaintiffs'

cancer because expert's cited study did not adequately support his opinion); *Nelson*, 243 F.3d at 252-54 (affirming exclusion of opinion that PCB exposure caused plaintiffs' injuries based on various flaws in expert's epidemiology study). In all of these cases, the experts' opinions were not "pulled from thin air"; the experts cited studies in attempts to support their opinions. Yet those opinions were excluded because the experts reached conclusions that were not adequately supported.

The cases Plaintiffs cite are not to the contrary. In *Jahn v. Equine Services, PSC*, 233 F.3d 382 (6th Cir. 2000), the court merely observed that the challenged experts did not "pull[] their notions from thin air," but instead had sufficient factual foundation for their opinions. *Id.* at 391. The court did not announce a "pulled from thin air" test for the exclusion of expert testimony. Similarly, in *In re Scrap Metal Antitrust Litigation*, 527 F.3d 517 (6th Cir. 2008), the court concluded that the expert had sufficient factual foundation for his use of a price index because it was undisputed that industry participants use the index. *Id.* at 531. And Plaintiffs' remaining case acknowledges that an expert's reliance on a study must be "rooted in some sound ground." *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 180 (D.N.J. 2020).

Perhaps recognizing the problems with Dr. Specht's China and Canada comparisons, Plaintiffs attempt to shift the focus to unidentified studies involving leaded gasoline exposure. Response 41-42, PageID.23367-23368. Dr. Specht did

not discuss leaded gasoline studies in his report, and it is not clear how that comparison supports his opinion that [redacted]. (Plaintiffs offer no explanation.) Plaintiffs cite Dr. Specht's testimony that leaded gasoline exposure can account for bone lead levels between 10 and 20 µg/g, apparently to suggest that a bone lead level above 10 µg/g [redacted]. Response 41, PageID.23367. But Dr. Specht was unable to point to any particular study on leaded gasoline as relevant here, and he conceded that the leaded gasoline studies involved "adult exposures" that "wouldn't be relevant" to Plaintiffs. Dep. 432:9-19. In any event, [redacted] so the comparison serves only to undermine Dr. Specht's opinion.

C. Dr. Specht Failed To Perform Any Control-Group Testing

Dr. Specht also could have attempted to make comparisons by testing a control group of children in or around Flint who were not exposed to lead as a result of the Flint water crisis.[10] Dr. Specht used a control group to evaluate bone lead levels in his China studies, but he departed from his past practice here. VNA Br. 38-39, PageID.21630-21631. That also undermines the reliability of his opinion.

[10] Plaintiffs argue that using a control group was "impossible" because of the delay in detecting lead in Flint's drinking water, Response 43, PageID.23369, but that is no answer because Plaintiffs have the burden of proving reliability. If Dr. Specht has nothing against which to compare his pXRF measurements on Plaintiffs, he cannot reliably opine that the measurements represent a "substantial" exposure.

Plaintiffs suggest that control groups are required or useful only for case studies. Response 43, PageID.23369. But the case law on control groups cited by VNA extends beyond the case-study context, VNA Br. 38, PageID.21630; use of control groups is good scientific technique. *See, e.g.*, Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 218-20 (3d ed. 2011) ("A good study design compares outcomes for subjects who are exposed to some factor (the treatment group) with outcomes for other subjects who are not exposed (the control group)"; "data from a treatment group without a control group generally reveals very little and can be misleading. Comparisons are essential."). Dr. Specht's failure to test a control group further illustrates that his opinion that his bone lead measurements show that Plaintiffs experienced [redacted] is unreliable.

III. Because Dr. Specht Cannot Trace Bone Lead To Particular Sources, His Opinions Would Not Be Helpful To A Jury And Would Be Substantially More Prejudicial Than Probative

VNA also moved to exclude Dr. Specht's bone lead measurements under Rules 402 and 403 because Dr. Specht cannot trace lead in Plaintiffs' bones to any particular source or time. The bone lead measurements cannot show that Plaintiffs were exposed to additional lead as a result of the Flint water crisis in general, let alone because of VNA in particular. As Dr. Hu put it, identifying the source of lead measured in bone is not "something that can be done." Ex. 15, Hu Dep. 386:8-11.

Dr. Specht does not disagree; he concedes that bone lead testing only shows cumulative exposures over many decades. Ex. 4, Specht Report (Report) 3-4.

Plaintiffs respond that Dr. Specht plays a "narrow role," that he seeks merely to opine that [redacted], and that other experts will do the rest to prove causation. Response 1, 3, 47, PageID.23327, 23329, 23373. But Plaintiffs' other experts do not trace lead in Plaintiffs' bones to the Flint water crisis or VNA, either. Dr. Graziano concedes that all children in America, including in Flint, have lead in their bodies. VNA Br. 41-42, PageID.21633-21634. And Dr. Specht admits that there has been no scientific conclusion as to what constitutes an elevated level of bone lead. Dep. 333:24-334:10. Without a reliable standard for what constitutes an elevated bone lead level, Dr. Specht's measurements are not probative of any fact in dispute. Even if they were, any marginal probative value would be substantially outweighed by the risks of jury confusion and prejudice.

Plaintiffs argue that Dr. Specht's bone lead measurements are necessary to rebut VNA's supposed position that "there is no proof that the Plaintiffs have been exposed to lead." Response 48, PageID.23374. But that is not VNA's position. Every child in America is exposed to lead to at least some extent. The issues here are whether Plaintiffs were exposed to harmful amounts of lead and whether those exposures were the result of the Flint water crisis generally and VNA's conduct in

particular. Dr. Specht's bone lead measurements will not help answer those questions.[11]

IV. Dr. Specht's Opinion About The Half Life Of Blood Lead Is Unreliable

To justify his use of *bone* lead measurements as proof of exposure, Dr. Specht seeks to discredit *blood* lead measurements—the standard measure for lead exposure that has been used in the United States for many decades. Dr. Specht opines that "[p]revious studies" have shown that the half-life of lead in children's blood is "less than one week," which Plaintiffs seek to use to explain away [redacted] and minimize the utility of blood lead. Report 3. As VNA explained in its opening brief, Dr. Specht's half-life opinion and the methodology that underlies it are unreliable because he never reviewed the literature on blood lead half-lives and instead relied only on two studies of his own that touched on the issue, which he then proceeded to embellish. VNA Br. 45-46, PageID.21638-21639.

Plaintiffs characterize VNA's argument as a credibility issue between different experts relying on different studies. Response 44, PageID.23370. But Plaintiffs ignore the fundamental flaw in Dr. Specht's methodology. If opposing

[11] Plaintiffs argue that a cautionary instruction is a better remedy than exclusion. Response 49-50, PageID.23375-23376. But if evidence is inadmissible, it should be excluded—not admitted with a cautionary instruction. Besides, a cautionary instruction could not cure the substantive problems with bone lead measurements, such as the admitted lack of any scientific conclusion about what constitutes an elevated level. A cautionary instruction also could not cure the potential confusion and prejudice from admitting Dr. Specht's measurements.

experts review the scientific literature and come to different conclusions, that may well be an issue for the jury to resolve "as to which picture of the science is correct." *Id.* But that is not what happened here. Dr. Specht looked only at his own research, not the "picture of the science," and he embellished the only two studies he did consider. VNA Br. 45-47, PageID.21637-21639 (collecting cases holding that cherry picking and embellishing are hallmarks of unreliability). Dr. Specht's blood lead half-life opinion is unreliable and should be excluded.

CONCLUSION

The Court should exclude the testimony and report of Dr. Aaron Specht.

Respectfully submitted,

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Dated: September 15, 2021

CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2021, I electronically filed the foregoing document with the Clerk of the Court using the ECF System, which will send notification to the ECF counsel of record.

Respectfully submitted,

/s/ James M. Campbell

Dated: September 15, 2021